



Lotus transducer

Instructions for use



Instructions for use – transducer

Before using the product, please read the following information thoroughly

Important

- This document provides instructions for using the Lotus Series 4 System. It is not a set of instructions for surgical technique.
- This document should be read in conjunction with the Lotus Series 4 User Manual.
- Failure to follow the instructions may lead to serious surgical consequences.
- The device is not provided sterile and must be washed and sterilized prior to use. Follow instructions set out in the “Lotus – Reprocessing instructions for reusable instrumentation” document.
- Store packaged devices in a cool dry area.

Caution

Federal (USA) law restricts this device to sale and use by, or on the order of a physician.



Symbol meanings

Symbol	Meaning
	Consult instructions for use
	Complies with Directive 93/42/EEC
	Catalogue Number
	Non-sterile
	Caution - Carefully read the instructions
	Temperature Limit
	Humidity Limitation
	Serial Number
	Date of Manufacture
	Manufactured By



Intended use

The Series 4 Lotus Coagulation and Cutting System is indicated for soft tissue surgical incisions when bleeding control and thermal injury are important. Series 4 Lotus may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional scalpels in general, plastic, urological, gynaecological, thoracic, exposure to orthopaedic structures (such as spine and joint space) and other endoscopic and open procedures.

Contraindications

The system is not indicated for cardiac surgery.

The handpiece is not indicated for coagulation and dissection of vessels larger than 5mm.

The device is not indicated for incising bone.

The device is not indicated for contraceptive tubal occlusion.



Steps for use

1. Ensure device has been cleaned and sterilized.
2. Ensure that the device is disconnected from the Generator.
3. Ensure that the jaw of the handpiece is in the open position with the trigger fully forward.
4. Insert the waveguide into the appropriate handpiece/sleeve. Refer to instructions provided with the single use handpiece/sleeve or the Lotus Series 4 User Manual.
5. Connect the transducer to the generator.
6. For operating technique of the full system refer to the Lotus Series 4 User Manual.



Warnings and precautions

1. Minimally invasive devices can vary in dimension from one manufacturer to another. If combining devices from different manufacturers always ensure compatibility prior to commencing the procedure.
2. Handle the device with care. Do not attempt to modify the device. Damage or changes can affect the ability to attain resonance and reduce the effectiveness of the device. Do not use if damage is suspected.
3. Blood and tissue may build up between the jaw and waveguide during surgery. This can cause the tip of the device to become abnormally hot. Remove any visible tissue build up from the device to prevent the increased risk of burn injury.
4. Ensure the jaw is closed when inserting the device into, and removing from, a trocar.
5. Do not bend the jaw backwards. Take care when inserting the device into a quiver.
6. As with all energy sources (Electrosurgery, Laser or Ultrasound) there are concerns over carcinogenic and infectious potential of the procedure by-products e.g. tissue smoke plume and aerosols. Effective protective equipment should be used for both open and laparoscopic procedures.
7. If the jaw becomes bent do not attempt to straighten it. Dispose of the device and open a new one.
8. If the waveguide touches anything metal while activated, sparks may be produced. Therefore, use caution when using in the presence of flammable gases or liquids.

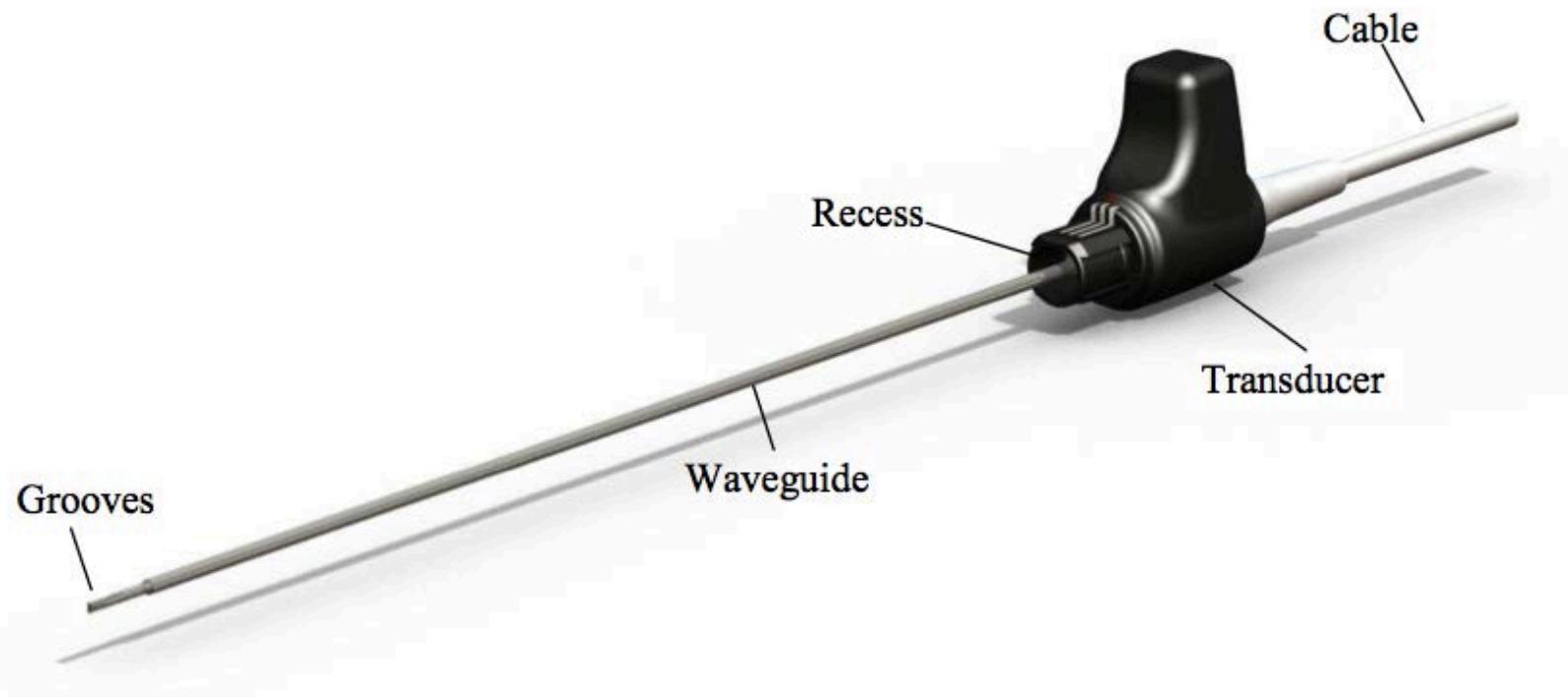


Warnings and precautions (continued)

9. If the waveguide touches anything metal or plastic while activated the device may become damaged.
10. Use only LOTUS accessories to assure compatibility.
11. This device should only be used by surgeons who are (1) trained in the types of surgical procedures that are to be carried out and (2) trained in the specific use of ultrasonic surgical instruments.
12. Ensure that electrical insulation or grounding is not compromised.
13. After significant activation, the distal end of the device may become hot. Do not allow the blade to contact tissue immediately following activation.
14. Do not allow the device to contact tissue while not in use, in case accidental activation should occur.
15. Care should be taken when operating in the vicinity of nerves.
16. The jaw liner may be damaged if the jaw is closed against an activated waveguide without tissue between them.
17. In case of equipment failure always ensure adequate back up equipment is available.
18. Do not use the device if the expiration date has passed or its sterility is compromised.

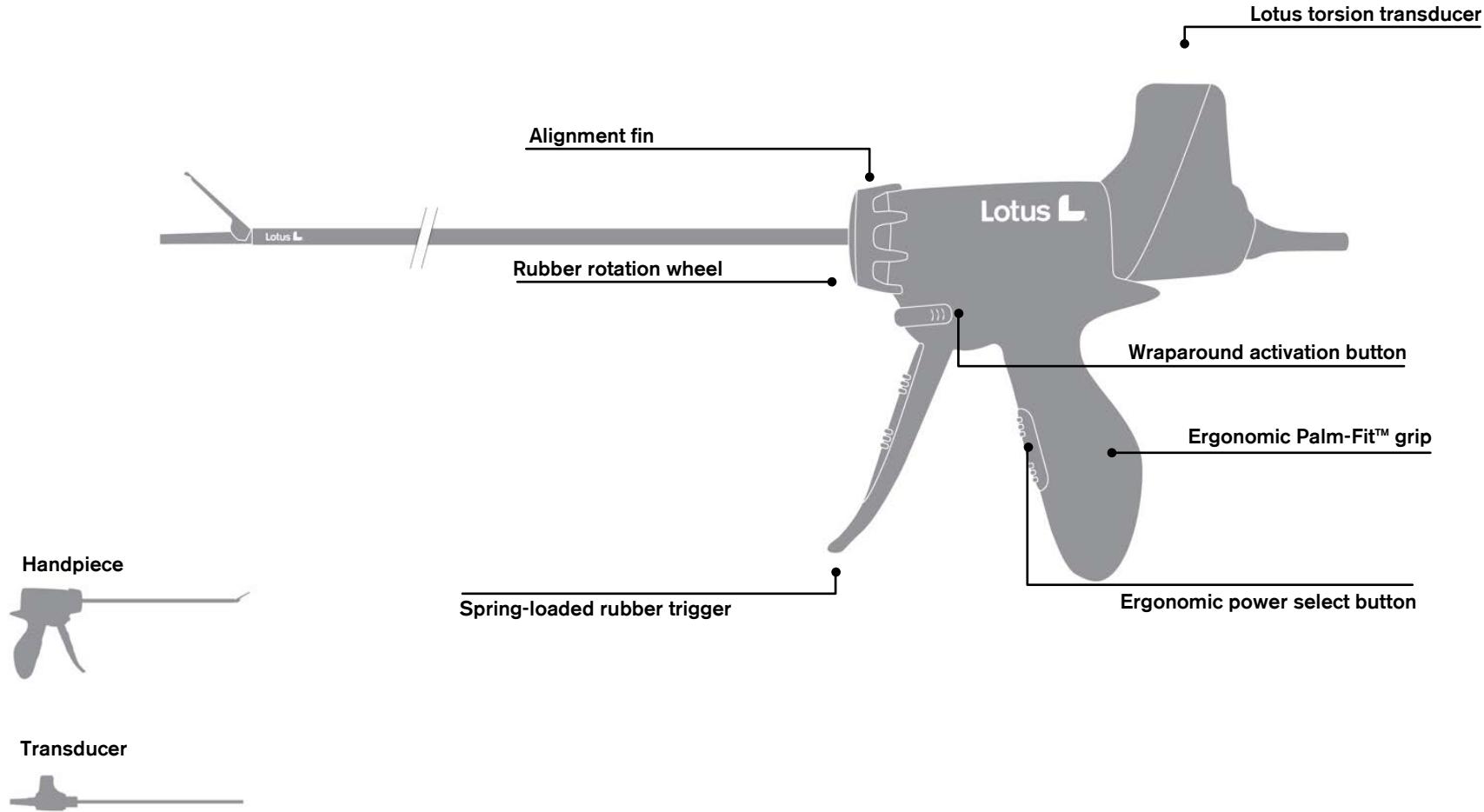


Transducer



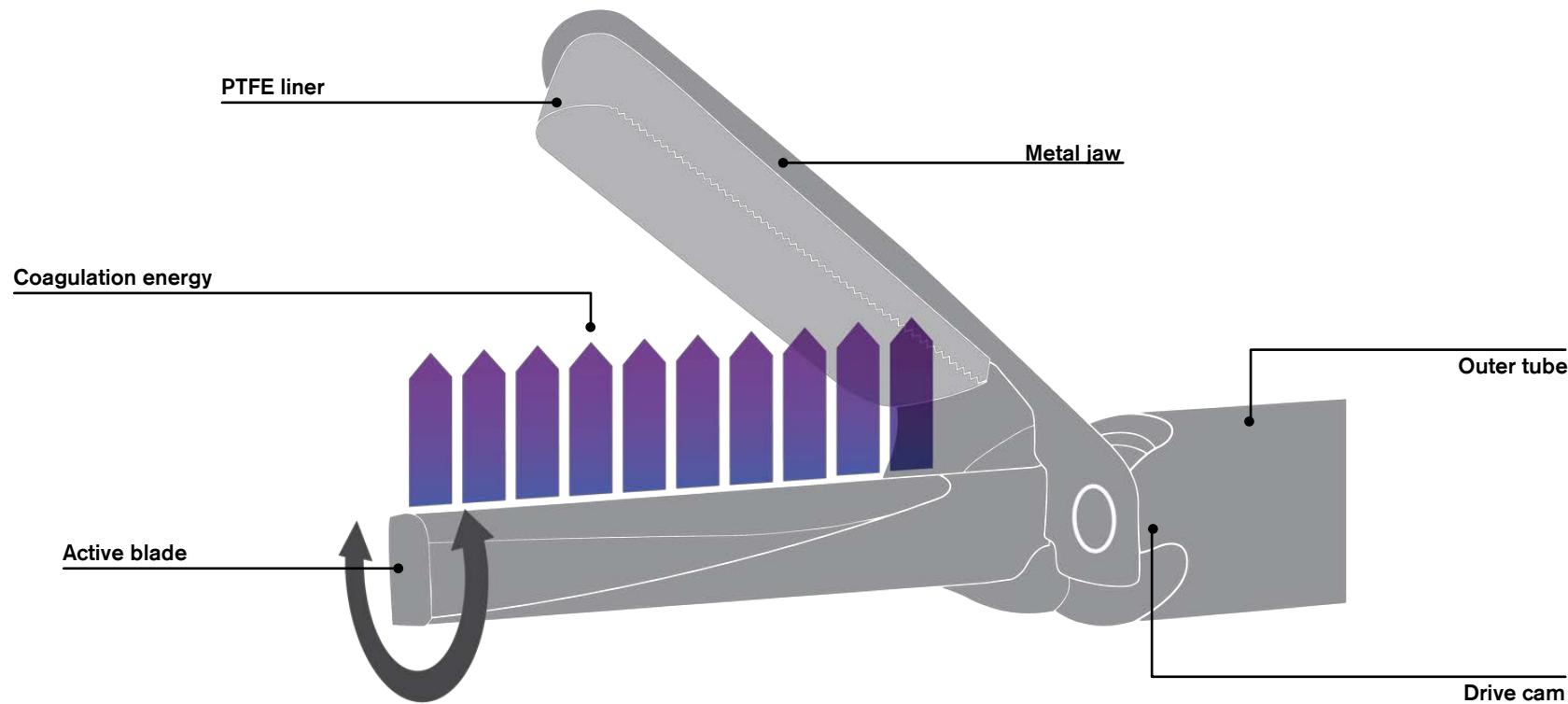


Transducer and handpiece





Distal tip schematic





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